

The Examiner objects to the term "surfaces" as vague in claims 1, 8 and 11-14. The Examiner is of the opinion that the claims do not specify the particular "entity" surface. The Examiner's attention is directed to the disclosure at page 12, lines 8-16, wherein it is disclosed that the surfaces referred to are all of those involved in the surgery (which limitation appears in the claims under rejection), namely, the tissue surfaces, surgical articles and the like. The claims specify coating the surfaces involved in the surgery which should be clear and definite to those skilled in the art.

The Examiner's attention is directed to the claim language employed in U.S. Patent No. 5,350,573 which is identical to that employed herein in this regard.

Inasmuch as the language is definite within the meaning of 35 USC 112 and inasmuch as the Patent and Trademark Office has approved such language in an issued patent, withdrawal of this ground of rejection is respectfully requested.

The Examiner has objected to the term "synthetic polymer" as vague. This term has a meaning well known to those skilled in the art. The Examiner's comment, "which ones?", appears to indicate that the Examiner's objection is more properly phrased under 35 USC 112, first paragraph, which is, indeed, the ground of rejection set forth at the top of page 3 of the Official Letter. It is respectfully submitted that the term is definite within the meaning of the second paragraph of 35 USC 112 inasmuch as it connotes a material

whose composition and structure is well known to those skilled in the art.

Accordingly, withdrawal of this ground of rejection is respectfully requested.

The rejection of claims 1-14 under 35 USC 112, first paragraph, is respectfully traversed. The crux of the Examiner's rejection appears to be that too few specific examples of the various generic groups of materials set forth in the claims are provided in the specification. The Examiner states that applicants' claim any polysaccharide, any synthetic polymer and any polypeptide. The Examiner goes on to state that the specification is insufficient to support the breadth of the claims. It is believed that the Examiner has overlooked a limitation appearing in the claims which drastically limits the scope of the above-noted generic definitions. The claims state that the material employed must be water-soluble, biocompatible and pharmaceutically acceptable. The claims also state that the material employed must have a molecular weight of about 50,000 D or above and that the material must be employed in a concentration of 0.01% to 15% by weight. It is further specified that the molecular weight and concentration must be such that the aqueous solution formed therefrom is capable of providing wet coatings on the surfaces involved in the surgery. Thus, applicants are not, as urged by the Examiner, claiming any polysaccharide, polymer or polypeptide. Only a relatively small number of these materials fit all of the criteria set forth in the claims,

namely, water-solubility, biocompatibility, pharmaceutical acceptability, molecular weight and concentration.

The Examiner has set forth no cogent reasons to question the objective enablement provided by the disclosure. Although the definitions employed in the claims encompass what the Examiner may consider to be a large number of materials, no reason or theory has been set forth to question why any of these materials would be inoperative or inappropriate in the method claimed.

It is well settled in patent law that a rejection of claims under 35 USC 112 is not sustainable even where expressions are considered broad if the same or substantially the same expressions appear in the disclosure and are exemplified by several representative materials. In the absence of reasons why the expressions would include materials inoperative for applicants' purposes, the representations set forth in the specification of materials included within broad expressions is considered to be adequate. See Ex parte Laiderman, 175 USPQ 757, and In re Mayhew, 179 USPQ 42.

Applicants are aware that a specification which "describes" does not necessarily also "enable" one skilled in the art to make or use a claimed invention. However, a rejection for lack of enablement under the first paragraph of 35 USC 112 must be substantiated with reasons. Section 112 does

not require that a specification convince persons skilled in the art that the assertions therein are correct. It is incumbent upon the Patent and Trademark Office, whenever a rejection on this basis is made, to explain why it doubts the truth or accuracy of any statement in a supporting disclosure and to back up assertions of doubt with acceptable evidence or reasoning which is inconsistent with the contested statement.

The only relevant concern of the Patent and Trademark Office under these circumstances should be over the truth of any such assertion. The first paragraph of Section 112 requires nothing more than objective enablement. How such a teaching is set forth, either by the use of illustrative examples or by broad terminology, is of no importance. See In re Armbruster, 185 USPQ 152; In re Dinh-Nguyen, 181 USPQ 46; and In re Anderson, 176 USPQ 331.

A rejection based on an insufficient disclosure cannot be maintained solely on the basis that the number of claimed compounds exceeds those specifically disclosed in the specification or that an inadequate number of specific examples are presented. In the absence of the Examiner's failure to present evidence which refutes applicants' statement or which shows that any of the claimed compounds are outside the specification's teachings dictates a withdrawal of this ground of rejection.

The Examiner is again reminded that the primary and critical limitations are set forth in the claims, namely, water-solubility, biocompatibility, pharmaceutical acceptability, molecular weight and concentration. The nature of the material employed beyond these limitations is relatively non-critical. It is important to note that the Examiner has presented no reason whatsoever as to why materials meeting these limitations and not specifically exemplified in the specification would be inoperative for the purposes stated. Inasmuch as the claims recite all of the necessary and critical limitations and inasmuch as the claims are commensurate in scope with the enabling disclosure insofar as the first paragraph of 35 USC 112 requires, withdrawal of this ground of rejection is respectfully requested.

The rejection of the claims under 35 USC 112, first paragraph, on the ground that applicants are entitled to claim only polyelectrolyte polysaccharides is respectfully traversed for the reasons set forth hereinabove. Again, the Examiner has set forth no reason for doubting the operability of polysaccharides satisfying the limitations set forth in the claims of water-solubility, biocompatibility, pharmaceutical acceptability, molecular weight and concentration. In the absence of cogent reasons for doubting the statements made in the specification, withdrawal of this ground of rejection is respectfully requested.

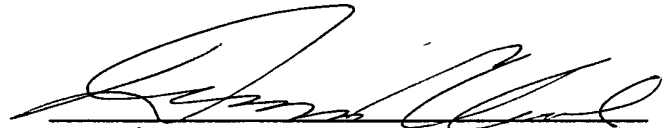
Applicants submit herewith a Terminal Disclaimer in response to the rejection of claims 1-4 under the judicially created doctrine of obviousness-type double patenting. An executed copy of the Terminal Disclaimer will be filed in due course. Accordingly, withdrawal of this ground of rejection is also respectfully requested.

Applicants have earnestly endeavored to place this application in condition for allowance, and an early action toward that end is respectfully requested.

To the extent necessary, applicants petition for an extension of time under 37 CFR §1.136. Please charge any additional fees due (or credit any overpayment thereof) to Deposit Account No. 11-0610 (Docket No. 4733).

Respectfully submitted,

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